

(and a progress report regarding milestones that have been completed) will be forwarded through command channels to the commander originally granting the waiver.

(iii) A request for amendment will be initiated when factors or circumstances requiring a change to the original waiver are identified.

(iv) When factors or circumstances prevent correction of the waiver condition within 5 years of the initial approval of the waiver, such condition becomes a candidate for an exemption.

(d) Exemptions. (1) Exemptions are relatively long-term exceptions to otherwise mandatory standards. Exemptions will be granted only under the following conditions:

(i) If corrective measures are impractical.

(ii) If impairment of the overall defense posture would result.

(iii) If positive programs to eliminate of the need for the exemption are being pursued.

(2) Exemptions can be approved only by the Secretary of the Army.

(i) Requests for exemptions will be sent through command channels to HQDA, DACS-SF, WASH DC 20310-0200.

(ii) Exemption requests will include the information required in paragraph(c)(2) of this section.

(iii) Copies of exemption requests will be maintained at the installation and MACOM or USAMRDC Safety Offices.

Subpart C—BDP Contractors

§ 626.15 Written procedures for contractor review.

The contracting agency will prepare written procedures for reviewing contractor capability to safely perform BDP work with etiologic agents. The written procedures will describe the criteria and guidelines for preparing the facilities description, safety requirements, special procedures and techniques, inspection procedures, and MCE scenarios. These written procedures will be submitted to the contracting agency MACOM for review and approval.

§ 626.16 Contracting agencies.

Contracting agencies, in coordination with their respective Command safety offices will monitor contractor performance in meeting safety requirements.

(a) The contracting agency will establish an inspection program and schedule for all BDP contractors who perform contract work with BL-3 or BL-4. Inspections will be conducted by safety and health personnel. The schedule will include, as a minimum, the following:

(1) A pre-award inspection on site, prior to contract award, for initial contracts for BDP work requiring BL-3 or BL-4 operations. If during a pre-award inspection, major corrective measures are required, a reinspection is required prior to the beginning of contract operations.

(2) A pre-award inspection of follow-on BL-3 and BL-4 contracts.

(3) A pre-operational inspection if a major change in procedures, facilities, or equipment is made after the pre-award survey.

(4) Annual inspection of BL-3 and semiannual inspection of BL-4 contractor facilities, equipment, and operations.

(b) Pre-award surveys and annual inspections of contractors performing work requiring BL-3 or BL-4 will be conducted by safety and health professionals trained in BDP operational safety requirements. Pre-award surveys and annual inspections of BL-1 and BL-2 contractors will be conducted by safety and health professionals or contracting agency representatives who are trained in biological safety inspection techniques. The Safety Inspection Checklist in DA Pam 385-69 will be used.

(c) The contracting agency will require each BDP contractor whose contract requires the use of etiologic agents to prepare a facility safety program plan based on the criteria below and submit the plan to the contracting agency for review prior to beginning BDP contract operations. The plan will describe the contractor organization, and procedures for meeting DOD, Army, and contracting Command safety requirements as specified in the contract.

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(1) A safety training program for all individuals working with etiologic agents must be documented by the contractor and include, as a minimum, the requirements in § 626.7(e). Appropriate safety training will be provided to scientists, other laboratory personnel, and unrelated personnel such as technicians, clerical, and maintenance workers. This training will be documented.

(2) The contractor must designate a qualified individual to be responsible for the entire safety program with full authority to develop and enforce contractor safety policies. Regular safety inspections will be conducted and inspection reports will be provided to the contracting agency upon request.

(3) Policies for storing, handling, and moving etiologic agents within the contractor facility shall be included in the plan.

(4) Policies and procedures for disposal of any etiologic agent waste must be identified. Disposal must comply with Federal, State, and local regulations as well as DOD and Army requirements.

(5) An SOP must be established for each area where BDP etiologic agents are stored, transferred, or used. In addition, an SOP must be prepared for operations unique to any specific contract. The contractor will provide the SOP to contracting agency personnel upon request for review.

(6) For contracts requiring BL-3 or BL-4, the contractor will provide (upon request) facility engineering drawings and specifications for the relevant etiologic agent containment areas, associated ventilation systems, and local approving authority. Also to be included is test data verifying that all systems adequately meet the DOD and Army safety requirements, as well as test methods for periodic recertification of the system.

(7) MCE scenarios that ensure that all realistic threats are considered at contractor sites, see § 626.12 of this part.

§ 626.17 Contractor changes.

The contractor will submit proposed changes to the original safety documentation to the contracting agency for review prior to implementation. Requests will include justification and

test data verifying that adequate safety will be maintained.

§ 626.18 BDP contract requirements.

(a) Contractors performing work with BL-3 and BL-4 material must prepare a plan detailing procedures for controlling laboratory mishaps involving etiologic agents.

(1) The contractor shall have the necessary equipment and trained personnel for controlling the mishap.

(2) In the event of an incidental release of a BDP etiologic agent from appropriate laboratory biocontainment that may result in personnel exposure, approved emergency procedures will be initiated immediately to effectively protect personnel and the environment and to constrain the spread of contamination. The affected areas will be decontaminated before normal operations are resumed.

(3) Special medical surveillance will be started as soon as possible for all workers present in the potentially affected area at the time of the mishap.

(4) Local emergency support agencies, such as law enforcement, fire departments, health departments, and governments will be informed of BDP activities and the appropriate support necessary, to include any equipment and training to provide effective emergency response. Agreements with external agencies must be formalized.

(5) The contractor shall be required to review the plan annually and consult external agencies if there is an agreement for them to provide assistance. This should be done in coordination with the contracting agency.

(b) [Reserved]

Subpart D—BDP Studies and Reviews

§ 626.19 Assuring maximum safety.

(a) Safety studies and reviews are conducted to assure that maximum safety and health measures are being taken to prevent mishaps involving BDP etiologic agents in any amount or under any conditions that may cause incapacitation, illness, or death to any person, or adverse effects on the public or to the environment.